CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INITIAL STATEMENT OF REASONS FOR THE PROPOSED AMENDMENT OF THE CIRM GRANTS ADMINISTRATION POLICY FOR ACADEMIC AND NON-PROFIT INSTITUTIONS

HEARING DATE: SEPTEMBER 22, 2008

SUBJECT MATTER OF PROPOSED REGULATIONS: CIRM Grants Administration Policy for Academic and Non-Profit Institutions

SECTIONS AFFECTED: The proposed amendment is to the document incorporated by reference into Chapter 5 and Section 100500 of Title 17 of the California Code of Regulations and is reflected in the reference to that document in subdivision (a) of Section 100500.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH AMENDMENT:

SECTION 100500 – GRANTS ADMINISTRATION POLICY:

Purpose:

The purpose of Section 100500 is to describe the terms and conditions that govern grant awards from the California Institute for Regenerative Medicine ("CIRM") to academic and non-profit institutions. The amendments are to the document incorporated by reference through subdivision (a) of Section 100500: CIRM's Grants Administration Policy for Academic and Non-Profit Institutions. The only amendment to Section 100500 itself is to correct the reference to the document incorporated by reference through subdivision (a).

Rationale:

Title 1 of California Code of Regulations, Section 20, permits agencies to incorporate by reference documents under certain conditions. Subdivision (c)(1) of that regulation allows such incorporation when to do otherwise be "cumbersome, unduly expensive, or otherwise impractical" to publish the document in regulatory form. In light of the size and magnitude of the policy and given the burdens associated with translating each of the document's separate provisions into specific regulations, incorporation by reference serves the needs of both efficient use of resources, avoids the cumbersome task of rewriting an entire manual, and avoids the risk of inadvertent disagreement between the regulations and the policies being implemented.

DOCUMENT INCORPORATED BY REFERENCE:

CIRM GRANTS ADMINISTRATION POLICY FOR ACADEMIC AND NON-PROFIT INSTITUTIONS
VERSION: with a footer that dates the document as "Non-Profit and Academic Institution Grants Administration Policy – July 15, 2008".

Preface:

The amendments to this section are clarifications that work in tandem with the changes to Section I including the abbreviations and glossary of defined terms. The term "Recipient" has been added in addition to "Grantee". As detailed in the glossary of defined terms, the term "Recipient" is defined as any person or entity that receives CIRM funding, including, for example, consultants and subcontractors as well as the Principal Investigator and Program Director. In contrast, the definition of "Grantee" is now limited to the academic or non-profit institution that is primarily responsible for the administration of CIRM funds and the proper conduct of the research. These definitions clarify who bears the burden of responsibility according to CIRM regulations. The distinction also helps CIRM with enforcement and tracking the use of CIRM funds from the institutional level all the way to the subcontractor level.

Likewise, the Preface has been amended to use the term "Project Period" as opposed to "Grant". This distinction is important because under Proposition 71, CIRM funding may come in the form of grants, loans or contracts. The amendments also explain how amended regulations are applied to currently active awards and alert readers to relevant sections in the California Code of Regulations.

SECTION I. GENERAL INFORMATION:

Purpose:

The amendments to this section are clarifications and additions to the abbreviations and glossary of terms used throughout the document. Throughout the Grants Administration Policy for Academic and Non-Profit Institutions (Non-Profit GAP or the Policy), funding in the form of a "contract" has been added alongside "grants" and "loans".

Also included is an amendment that allows for the possibility of specific programs for which CIRM's President, rather than the Scientific and Medical Research Funding Working Group ("Grants Working Group" or "GWG"), will review proposals.

Rationale:

The amendments to this Section I make specific the language and terminology used in these regulations. The addition of the term "contract" is necessary to conform to Proposition 71, which allows for funding to come in the form of contracts as well as "grants" or "loans."

In the last sentence of Section I.A. the phrase "in the State of California" was added to make it explicit that the stem cell research facilities funded must be located in California.

The abbreviation "ESCRO" is eliminated as redundant because "ESCRO" and "SCRO" share the same meaning. The abbreviation for the Scientific and Medical Research Funding Working Group is changed from "SMRFWG" to "GWG" for brevity.

A new provision creates an exception that authorizes the President of CIRM to review specific types of research education proposals seeking funding of less than $100,000. In these circumstances it does not make economic or scientific sense to convene a GWG session.

Section I.C. Glossary of Defined Terms:

Purpose:

Amended to define "Authorized Executive Official" and "CIRM–funded Project or Activity". Amended to define "Consultant" and clarify that a Consultant is governed by these regulations. Amended to define "Facility or Facilities" consistent with the definition adopted as part of CIRM's Facilities Grants Administration Policy, Section 100700. Amended to delete the definition of "Full-Time Appointment" because eligibility requirements change with each Request for Application (RFA) and are best defined therein. Amended to define "Non-profit and Not-for-Profit". The definition of "Operation and Maintenance Expenses" was amended to clarify allowed costs. Amended to define "Recipient" and clarify that Recipients are governed by these regulations. Amended to define the terms "GWG" and "Subcontract".

Rationale:

These amendments make specific the language and terminology used in these regulations. Some of the amendments are new definitions, some are non-substantive changes and others clarify existing definitions that are ambiguous. All of the amendments are important to ensure consistent interpretation of the defined terms throughout the CIRM regulations.

The definition of "Authorized Executive Official" (AEO) is new and in addition to the defined term "Authorized Organizational Official" (AOO). An AEO, unlike an AOO, must have legal authority to commit a Grantee institution's funds and resources. In order to ensure proper oversight of CIRM funds, appropriate individuals within the applicant institutions must be identified and charged with assuming responsibility for compliance with the Policy.

The addition of "CIRM-funded Project or Activity" is important as CIRM may be funding grants, contracts or loans and the definition clarifies that if CIRM is only funding a portion of the project, then the Policy and CIRM regulations will still apply to the project.

The definition of "Consultant" is in contrast to the definition of "Subcontractor" and distinguishes the different services each may provide. The service provided by a Consultant is advice. A Subcontractor performs a discrete and specialized piece of the proposed research.

The definition of "Full Time appointment" is deleted from the Policy because it will now be defined as appropriate to each RFA. Experience has shown that appropriate eligibility criteria will vary depending on the nature of the research program funded, and that a full time appointment is not a necessary threshold of eligibility for all funding opportunities. The deletion of the definition from the Policy allows CIRM the flexibility to attract the most talented and qualified individuals to serve as Principal Investigators on research grants.

The amendments to "Operation and Maintenance Expenses" clarify the components of these types of expenses that CIRM will fund. CIRM has conformed its definition of "Operation and Maintenance Expenses" with Federal OMB Circular A-21.

The definition of "Progress Report" was deleted and replaced as imprecise. Reporting requirements are the subject of Section V.H which includes Programmatic Reports that address progress measured against stated research aims as well as financial reports that address use of CIRM funds.

Section I.E.2. Roles and Responsibilities – Grantee Organization Staff:

Purpose:

The amendments to this section delete a description of the Director of Scientific Activities and clarify who is an Authorized Executive Official and what legal authority they must possess.

Rationale:

These amendments augment and clarify the appropriate individuals within a Grantee institution that are responsible for compliance with pertinent rules. The definition and reference to "Director of Scientific Activities" is no longer descriptive of the role within CIRM's staff and is therefore deleted. The definition of "Authorized Executive Official" is added. The amendments to this section alert institutions that the designation of such an Authorized Executive Official confers apparent authority on that official, including the authority to commit the institution to defend and indemnify CIRM.

SECTION II. GRANT APPLICATION AND REVIEW PROCESS.

Purpose:

Subpart B. Application Submission: The amendments to this subpart clarify the documents that CIRM may require as a condition of submission of an Application.

Rationale:

The amendments to subpart B bring the regulations into conformance with the Application process and make each step in the process clear to potential applicants. The amendments state that CIRM may request a "Candidate Nomination Form" (CNF) or a Letter of Intent as a condition of submitting an Application. In circumstances where CIRM limits the number of Applications that may be submitted, the CNF allows an applicant institution to identify the individuals it authorizes to submit Applications in response to a particular RFA.

Purpose:

Subpart D. Application Review: The amendments to this subpart change the meaning of designating an application to Tier 2- Provisionally Recommended for Funding.

Rationale:

The change to this designation stems from a balance of the factors that are reviewed by the Grants Working Group (GWG) as opposed to the factors that are evaluated by the Independent Citizens Oversight Committee (ICOC). Specifically, this designation has been amended to give the GWG greater flexibility in communicating to the ICOC its scientific and programmatic evaluation of the applications under review. For example, this flexibility would allow the GWG to alert the ICOC that these applications are recommended for funding only if the ICOC makes a programmatic decision that the research is meritorious in light of the overall funding plan; or that this group of applications is recommended for funding only if funds are available. The ICOC is the final decision maker on funding for all Grants.

Purpose:

Subpart E. Criteria for Review. The amendments to this subpart clarify that the GWG criteria for review or their weighting of the criteria for review may be changed after issuance of the RFA.

Rationale:

The amendments to subparts E & G specify the expectations for Applicants during the grant application and scientific review process and what they can expected of the GWG, CIRM and the ICOC during the evaluation of Applications.

Purpose:

Subpart F. Appeals of Scientific Review: The amendments to this subpart align the Policy with CIRM's Conflict of Interest regulations, Section 10000 through 100004. There is also an amendment that specifies appeal procedures and distinguishes between an informal appeal to the Scientific Review Officer and a formal written appeal. The amendment also clarifies that CIRM's President has the authority to determine if an appeal is meritorious, and slightly changes the procedure for re-review if the appeal is granted. If the President decides that an appeal is meritorious, then two scientist members of the GWG will do the reevaluation.

Rationale:

The amendments to subpart F clarify the appeals process and streamline the re-review procedure in the event that an appeal is found to be meritorious. The change to the procedure for re-review is necessary to avoid extended delays. Under the new procedure, re-review will be performed by two scientist members of the GWG, rather than the entire GWG, which will be as effective but more efficient. The results of re-review will go to the ICOC, which will make all final funding decisions.

SECTION III. PRE-AWARD AND AWARD.

Purpose:

Subpart A. Administrative Review: The amendments to this subpart clarify that CIRM will revise budget items in conformance with this Policy instead of requiring the Applicant to make such changes and that any issues that arise during administrative review must generally be resolved before CIRM will issue a Notice of Grant Award (NGA).

Rationale:

The amendments to subpart A are necessary for clarity and consistency. They also give CIRM flexibility in processing applications approved for funding, allowing CIRM to be more nimble in response to research needs.

Purpose:

Subpart B. Liability: The amendments to this subpart clarify that if a Grantee fails to provide evidence of insurance prior to issuance of the NGA then by execution of the NGA it will be deemed to have agreed to indemnify CIRM.

Rationale:

The amendments to subpart B specify when proof of insurance is required and that an institution that fails to provide such proof is deemed to have agreed to defend and indemnify CIRM in conformance with Proposition 71. Having Grantee institutions bear the burden of either

providing proof of insurance or agreeing to defend and indemnify CIRM protects the Public and ensures that research is not delayed unnecessarily.

Purpose:

Subpart C. Public Policy Requirements: The amendments to this subpart clarify the deadlines for submitting documentation of public policy assurances, and permit CIRM to issue a NGA subject to a condition subsequent. The amendments also clarify that Grantees must retain documentation for longer than five years where there are unresolved audit findings. Throughout subpart C, the term "Recipient" has been added in addition to the term "Grantee". In subpart C.4 the amendments clarify the information that should appear in a Stem Cell Research Oversight Committee (SCRO) approval. In subpart C.6.c the amendment clarifies that compliance failures are grounds for CIRM to withhold further funding. In subpart C.6.e the amendment adds responsibility for Serious Adverse Event Reporting to conform to the federal standard imposed by the Food and Drug Administration ("FDA"). In subpart C.9 the amendment updates the references to CIRM's Intellectual Property policies, which have since been codified as regulations. Subpart C.10 is the Preference for California Suppliers. The amendment to this section is a placeholder indicating the definition of the term "California Supplier" is being separately considered as an interim regulation.

Rationale:

The amendments to Section III.C allow CIRM to issue a NGA subject to a condition subsequent. When research requiring public policy assurances will not begin in the first year of the Project Period, it is not efficient or timely to require those assurances at the outset of the Project Period. Instead, the NGA can be issued subject to the condition that before the research phase requiring public policy assurances begins, the Grantee must provide CIRM evidence of such assurances, and that no CIRM funds may be used for that research until such assurances are provided. This amendment will alert potential Grantees that a conditional NGA is an available option for processing documentation in a timely manner.

Beginning in subpart C.1, the term "Recipient" has been added to "Grantee" to clarify that the Policy applies to all individuals who are budgeted recipients of CIRM funds and not just to the institution whose name is on the check. For example, Subcontractors are also required to provide Public Policy assurances and comply with CIRM's Medical and Ethical Standards.

Similarly, in subpart C.2, the term "contractor" was added to refer back to definition in the glossary of terms and clarify that conflict of interest safeguards apply to both contractors and consultants.

Amendments subpart C.4 specify the information that must be documented in Stem Cell Research Oversight Committee (SCRO) and Institutional Review Board (IRB) assurances. These additions will help Grantees produce the clear and accurate records that CIRM needs to evaluate whether the Grantees are in compliance with CIRM regulations.

Subpart C.6.e adds a requirement (consistent with FDA standards) for Serious Adverse Event Reporting. This requirement is essential to alert CIRM to potential problems associated with

clinical trials in a timely manner. This addition is being made now in anticipation of CIRM funding clinical trials. The requirement of Serious Adverse Event Reporting is a standard practice within the industry and CIRM is bringing the Policy into conformance with that standard.

Deleted from subpart C.6.d and C.7.e are requirements for a report when human and animal subjects are no longer part of the project. New language in each of those subparts clarify that CIRM will not authorize continued funding without current and complete documentation for the research. This revised protocol is more efficient for CIRM and is as effective to ensure compliance with the Policy. Grantees are alerted that CIRM will review the file when progress reports are due to ensure that all required assurances are updated. With these amendments, Grantees are now on notice that CIRM will not advance further funding until the necessary documentation is provided.

The amendment to subpart C.9 updates the references to CIRM's Intellectual Property policies to reflect their final adoption and thereby improves the clarity of the Non-Profit GAP by alerting the readers to the code section they should reference.

Purpose:

Subpart D. Just-in-Time Policy: The amendments to subpart D.2 clarify that CIRM will review documentation of Other Support received by Principal Investigators and Program Directors.

Rationale:

To conform the Non-Profit GAP to the standards of comparable agencies, CIRM will primarily review information about other research funding support for Principal Investigators and Program Directors during the Project Period. However, CIRM reserves the right to request Other Support information on additional key personnel if that information is necessary for evaluating compliance with CIRM regulations.

Purpose:

Subpart E. Award Notice: The amendments to subpart E state that CIRM will send one Notice of Grant Award to the Authorized Organizational Official or the Authorized Executive Official and that it will no longer send a duplicate copy to the Principle Investigator or Program Director.

Rationale:

The amendments to subpart E conform the Policy with standard practice among comparable agencies. The amendments to this subpart also make specific reference to the incorporation of all applicable CIRM regulations into the Notice of Grant Award

The amendments to the subdivisions of Section III are necessary to clarify the practices of Administrative Review and the indemnification and public policy assurances that CIRM requires from Grantees. The Section III amendments also help to ensure adequate compliance with

federal and state laws governing certain types of research and to follow the remedies for research misconduct promulgated by NIH and others. Further, the amendments are necessary to ensure compliance with requirements imposed on CIRM to track the research that CIRM funds and to ensure that the research complies with applicable statutes and regulations.

The ICOC is in the process of considering an interim regulation to define the term "California Supplier". If an interim regulation is adopted, it will be properly noticed.

SECTION IV. AWARD ACCEPTANCE.

Purpose:

The amendments to this section clarify (a) that a NGA must be signed and returned within 45 days and (b) that because urgency is core to CIRM's mission NGAs must have a start date no later than six months after funding approval by the ICOC, in the absence of a waiver.

Rationale:

The amendments to this section are necessary to inform Grantees of the timing requirements applicable to their Award.

The change to the deadline for returning a signed NGA reflects CIRM's experience. Institutions have had difficulty achieving the existing deadline. Further, the amendment allows CIRM the flexibility to impose a deadline of fewer than 45 days when a shorter time period is consistent with the terms of the grant. For example, a shorter time period might be appropriate when the Project Period for the Grant is less than a year.

The urgency language was added in recognition of CIRM's limited life span. The amendments alert Grantees of the shorter time lag between Award and funding than that which Applicants may be accustomed to from working with other funding agencies. Applicants can use this information in planning their research funding schedule even as they are applying for grants.

SECTION V. PAYMENT AND USE OF FUNDS.

Purpose:

Subpart B. Costs and Activities: The amendments to subpart B.1 clarify that Subcontracts or Consulting Agreements with individuals or organizations located outside the State of California must be justified and are limited to specific dollar amounts. The amendments to subpart B.4 include clarification that Unallowable Facilities Costs include costs already provided by other sources, including grants awarded under CIRM Major Facilities Program RFA 07-03. The addition of subpart B.6 explains the records that are required related to interest earned on CIRM Funds.

Rationale:

The amendments to subpart B.1 recognize that although, as a general rule, CIRM funds used for consulting and subcontracting generally must be spent on work done in California, there are some limited circumstances in which funds can be spent outside the state in the service of the research. The salary cap for Principal Investigators, Program Directors and Key Personnel is adjusted from the amount stated for 2006 in keeping with the Policy's authorization of an adjustment based on the California Consumer Price Index. The new figure is current for 2008. In addition, the date for adjustment of the cap has been changed from January 1 to June 1 because California Consumer Price Index information is not readily available on January 1 of each year.

The amendments to subpart B.4 specify Unallowable Facilities Costs. The amendments reflect policy adopted by the ICOC to carry out the purposes of Health & Safety Code section 125292.10(u). The amendments also conform the Policy to related CIRM policies including California Code of Regulations section 100700 and 100701 (respectively the Grants Administration Policy for Facilities and Equipment Grants and the Grants Administration Policy for Academic and Non-Profit Institutions - Major Facilities Grants. These amendments are consistent with standard NIH practice for recovering indirect costs related to facilities.

The additions to subpart B.4 also specify the research that must be conducted in a CIRM funded facility. CIRM will track the time periods and amounts in the facilities part b calculation and will allow restoration of funding at the appropriate time. The details in these amendments are vital for Grantees' understanding of how CIRM will fund research to be performed in CIRM funded facilities.

The addition of subpart B.6 on interest earned on CIRM Funds conforms the Policy to current practice by similar agencies. CIRM had already required such information but the requirement was previously stated in each NGA and is now being noticed in the Policy.

Purpose:

Subpart C. Budgetary Overlap: The addition in this subpart includes clarification that Pre-Award costs are incurred at a Grantee's risk.

Rationale:

The amendments in subpart C conform the Policy to standard grant making practice at NIH. The amendments interpret and make specific Grantees ability to incur Pre-Award Costs on certain conditions. These amendments support CIRM's mission to move as expediently as possible.

Purpose:

Subpart D. Prior Approval Requirements: The amendments to subpart D.4 clarify that the Grantee may make pre-funding budget change requests. The additions to subpart D.5 clarify the process by which a Grantee may relinquish an Award as well as the process for requesting an Award transfer.

Rationale:

The amendments to subpart D.4 specify that CIRM will not permit budget adjustments that would increase the total Award above that approved by the ICOC. However, CIRM may permit budget adjustments that would decrease the total amount awarded by the ICOC.

In subpart D.5 the amendments clarify the steps required to relinquish an Award and transfer an Award.

Purpose:

Subpart E. Equipment Management: The amendments to this subpart eliminate the requirement that title to equipment vest in CIRM or vest with the Grantee only with CIRM's approval.

Rationale:

The changes to subpart E bring the Policy in conformance with standard practice among other granting agencies and eliminate legal complications for CIRM that are not necessary to properly administer the grants. The Grantee retains all obligations for equipment management and compliance and must obtain prior approval to transfer equipment.

Purpose:

Subpart F. Accounting Records, Documentation, Access to Records and Audits: The amendments to subpart F.4 specify that CIRM may require a Grantee to commission an independent audit of its accounting records at its own expense.

Rationale:

The changes to subpart F.3 identify the state agencies that are likely to require access to Grantees' records and that must be given such access. The addition in subpart F.4 of a potential requirement for an independent audit brings the Policy into conformity with CIRM's Grants Administration Policy for Academic and Non-Profit Institutions - Major Facilities Grants (California Code of Regulation section 100701.)

Purpose:

Subpart H. Reporting Requirements: The amendments to subpart H.2 specify the items that must be included in Progress Reports and states that CIRM will not issue payment for any subsequent budget period until it has received a Progress Report.

Rationale:

The changes to subpart H alert Grantees to applicable Reporting Requirements. The subpart H.3 amendment specifies the California Code of Regulations section that governs intellectual property. In subpart H.4 the time period for calculating whether a report is delinquent has been changed from 90 days to 60 days. The 60-day time period is consistent with CIRM's sense of urgency and with the other compliance time periods expressed in the Policy.

Purpose:

Subpart I. Grant Close-Out: The amendments to this subpart clarify that the Close-Out of an Award does not extinguish accountability requirements.

Rationale:

The amendments to subpart I specify that CIRM will close out an Award within 60 days of the Project Period end date. The previously stated "as soon as possible" was ambiguous. The amendments to subpart I further alert the Grantee to establish procedures for managing the obligations that continue after a Grant close-out. The deletion of the reference to Grantee's obligation to report to CIRM after close-out does not eliminate that obligation. The obligations continue and are just specified in other areas of the Policy along with the other CIRM regulations noted in the prior paragraph of subpart I.

Purpose:

Subpart J. Failure of Compliance: The amendments to this subpart specify that CIRM reserves the right to disqualify a Grantee or Principal Investigator from receipt of further CIRM funds for failures of compliance with CIRM regulations. The disqualification may be for a certain time period or indefinitely depending on CIRM's judgment of the compliance deficiency. For clarity, the amendments specify the code section for CIRM's Intellectual Property Regulations.

Rationale:

The amendments to these subdivisions of Section V are necessary to clarify the regulations and standards governing payment and use of CIRM funds.

SECTION VI. SPECIAL POLICIES FOR TRAINING GRANTS

Purpose:

Subpart B. Trainee Policy: The amendments to this subpart clarify that eligibility requirements for training grants will be found in the RFA.

Rationale:

The amendments to subpart B.2 delete the specific degree requirements for eligibility. As with its other grants, CIRM has learned that appropriate eligibility requirements vary with the requirements of each research program and are best delineated in a particular RFA. Likewise, deletions from subpart B.3 reflect that training periods will be specified on an RFA by RFA basis.

Purpose:

Subpart C. Allowable Costs and Activities for Training Grants: The amendments to this subpart clarify the direct costs and indirect costs allowable for Training Grants.

Rationale:

Required stipend levels are deleted from subpart C.1 because CIRM has learned that appropriate stipend levels vary with the requirements of each training program. In addition, CIRM expects that cost of living increases will cause the amounts to change over time. Some flexibility is required to permit these adjustments without having to undertake a regulatory change. The amendments to subpart C.2 and C.3 specify how tuition and fees and health insurance reimbursement calculations are to be made. Health insurance costs are included as part of tuition and fee costs for students who are not at the postdoctoral level or clinical trainee level. These amendments are important for financial accountability and to express appropriate limitations based on CIRM's knowledge of average tuition costs and the incorporation of health insurance fees into tuition and fees for undergraduate and some graduate level students.

The amendment of subpart C.4 will allow personal computers purchased with CIRM funds to be given to the Trainees on completion of the program. The relatively short lifespan and low cost of personal computers make this policy more reasonable than requiring institutions to store functionally obsolete machines.

Purpose:

Subpart D. Prior Approval Requirements for Training Grants: The amendments to subpart D.7 allow for collaboration among institutions with prior approval from CIRM. The amendments to subpart D.8 specify that CIRM may approve use of carry forward funds to increase the number of approved trainee positions.

Rationale:

The amendments to subpart D.7 anticipate future RFAs that will encourage collaboration among PIs from different institutions by allowing sharing of resources and credit. In general collaborations are consistent with CIRM's objectives and should be encouraged. The changes to subpart D.8 are in recognition of CIRM's experience with Training Grants. There will likely be unanticipated carry forwards including savings in health insurance costs and fees and interest earnings. Those carry forward funds may be enough to support an additional Trainee. Allowing additional Trainees is desirable for and consistent with CIRM's mission. The amendments make clear that prior approval is still required for additional Trainees.

Purpose:

Subpart E. Reporting Requirements for Training Grants: The amendments to subpart E.3.b clarify that a Trainee Termination Form must be completed for each Trainee. The amendments to subpart E.6 specify that Grantees must provide umbrella public policy approvals for all Trainees.

Rationale:

The amendments to subpart E.3.b require submission of a Trainee Termination Form. This form provides vital final information on Trainees and is the most expeditious way for CIRM and the Institution to memorialize the event.

The amendments to subpart E.6 clarify how institutional assurances for research by Trainees are to be submitted. CIRM's experience has been that the number of people administered under each Training Grant makes the provision of individual assurances for each Trainee unwieldy for both CIRM and the Grantee to administer. The amendments to this section streamline the process by allowing for one annual submission of public policy assurance documents that will cover all of the Trainees funded by the Grant during the Budget Period. This new method does not change the underlying documentation required for each institutional assurance. It merely changes how much documentation is submitted to CIRM and at what point in time.

In general, the amendments to Section VI specify the requirements necessary for effective and efficient management of the Training Grants.

SPECIFIC PURPOSE OF REGULATION AND FACTUAL BASIS FOR AMENDMENTS TO REGULATION:

The Grants Administration Policy for Academic and Non-Profit Institutions (Non-Profit GAP) is required for effective grants management by CIRM. Further, the Non-Profit GAP is necessary for meeting the specific reporting requirements of the California State Legislature and also for disseminating the outcomes of funded research to interested constituencies and the general public. The Non-Profit GAP outlines statutory requirements applicable to CIRM and its working groups and those governing CIRM-funded research. The Policy also serves to guide Academic and Non-profit Grant recipients on their responsibilities as CIRM Grantees. Principal investigators, Program Directors, and Organizational Officials with grants management responsibilities may refer to pertinent sections for answers to questions that arise concerning the administration of the awards and compliance protocols. The amendments to the Non-Profit GAP are necessary to achieve the requirements and purposes discussed above.

CIRM formulated the amendments to the Non-Profit GAP over time in response to requests for clarification from Grantees and after experience administering funding pursuant to the Policy. Changes were also made so that the Policy will continue to reflect current practices both at CIRM and at analogous agencies including the U.S. Food and Drug Administration and National Institutes of Health. On June 20, 2008, CIRM held a public discussion on the proposed changes to the Non-Profit GAP. Comments received from the public during that discussion, as well as written comments that were received, have been incorporated into the proposed amendments.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS:

CIRM did not rely upon any specific technical, theoretical or empirical studies, reports or documents in proposing the amendments to these regulations.

MANDATE FOR SPECIFIC TECHONOLOGIES OR EQUIPMENT:

The proposed amendments do not mandate the use of specific technologies or equipment.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES:

In view of information currently possessed, no reasonable alternative considered would be more effective in carrying out the purposes for which the amendments are proposed, or would be as effective as the amendments proposed.

CIRM invites interested persons to present statements or arguments with respect to alternatives to the proposed amendments at the scheduled hearing or during the written comment period.

REASONABLE ALTERNATIVES TO THE PROPOSED AMENDMENTS AND THAT WOULD LESSON ANY ADVERSE IMPACT ON SMALL BUSINESS:

CIRM has made the initial determination that the proposed amendments will not have an adverse impact on small business. The Non-Profit GAP applies to CIRM Grantees who are Academic Institutions and Non-Profit Institutions and who do not meet the definition of small business as defined in Government Code Section 11342.610.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS:

CIRM has made the initial determination that the proposed amendments will not have a statewide adverse economic impact.